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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,946	05/02/2001	Michael J. May	PPI-119	6173

959 7590 07/13/2005

LAHIVE & COCKFIELD, LLP.
28 STATE STREET
BOSTON, MA 02109

EXAMINER

DESAI, ANAND U

ART UNIT PAPER NUMBER

1653

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/847,946	Applicant(s) MAY ET AL.	
	Examiner Anand U. Desai, Ph.D.	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to Amendment filed on March 7, 2005. Claims 1, and 2 have been cancelled previously. Claims 3-13 are currently pending and are under examination.

Withdrawal of Rejections

2. The rejection of claims 3-5, and 7-11 under 35 U.S.C. 112, 2nd paragraph as being indefinite is withdrawn.

3. The rejection of claims 3-10 under 35 U.S.C. 102(b) as being anticipated by Rothe et al. (WO 99/01541) is withdrawn in view of Applicants amendment to the claims.

4. The rejection of claims 3-13 under 35 U.S.C. 103(a) as being unpatentable over Rothe et al. (WO 99/01541) in view of Applicants admission in the restriction/election response is withdrawn in view of Applicants amendment to the claims.

5. The rejection of claims 3-13 under 35 U.S.C. 103(a) as being unpatentable over Rothe et al. (WO 99/01541) in view of Schwarze et al. (Science Vol. 285, pp. 1569-1572 (1999)) is withdrawn in view of Applicants amendment to the claims.

Maintenance of Objections and Rejections

Claim Objections

6. Claims 3, 4, and 5 are objected to because of the following informalities:

There are two styles currently used to represent amino acids, suggest using three letter abbreviations throughout. For example, suggest in claim 3, X₁ is Leu, Ala, Ile ~~L, A, I~~ or nor-leucine (Nle).

In claim 4, X_a is Thr-Ala is not a variable since it recites a single member. Suggest placing the two amino acids in the structure listed.

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Appropriate correction is required.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 3-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, and 5 of U.S. Patent No. 6,864,355 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in U.S. Patent 6,864,355 B1 are drawn to an isolated peptide, identified as SEQ ID NO: 2, Leu-Asp-Trp-Ser-Trp-Leu, and a composition comprising an amino acid sequence that is less than 100 amino acids in length, and the claims of the currently pending application are drawn to a compound comprising a structure that encompasses the identified amino acid sequence, Leu-Asp-Trp-Ser-Trp-Leu (current application, claims 3-13).

Response to Remarks

Applicants state they will consider submitting a terminal disclaimer. The claims are currently rejected because no terminal disclaimer is currently of record in this application. The claims are obvious because one of ordinary skill in the art would expect a disclosed amino acid

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comprising the same sequences to inherently possess the function based on the structure of the peptide.

Art of Record

Rothe et al. (WO 99/01541) does disclose the amino acid sequences of human IKK- α , which are 756 (SEQ ID NO: 2) and 745 (SEQ ID NO: 4) amino acids in length. Rothe et al. (WO 99/01541) does not teach or suggest a NEMO binding domain within IKK- α , and therefore does not disclose an anti-inflammatory compound that is less than 100 amino acids in length.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

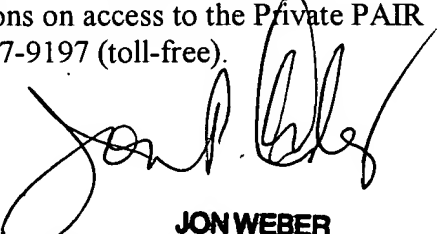
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 7:00 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

July 8, 2005



JON WEBER
SUPERVISORY PATENT EXAMINER